

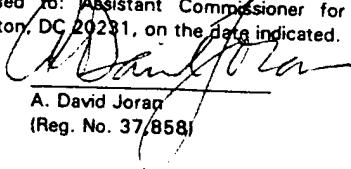
04/12/01  
09/033327  
JC929 U.S. PTO



**CERTIFICATE OF MAILING**

I hereby certify that this paper and every paper referred to therein as being enclosed is being deposited with the U.S. Postal Service as first class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on the date indicated.

July 8, 1999  
Date of Deposit

  
A. David Jorap  
(Reg. No. 37/858)

File No.: 1078/1B925US1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Samuel J. Danishefsky *et al.*

Serial No.: 09/042,280

Group Art Unit: 1623

Filed: January 13, 1997

Examiner: Lee, H.

For: COLON CANCER KH-1 AND N3 ANTIGENS

July 8, 1999

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and §1.97, applicants wish to direct the Examiner's attention to the following disclosures of which applicants have become aware, or which were cited by the International Searching Authority in connection with the related PCT International Application:

1. V. Bencomo et al., "Synthesis of glycopeptides having clusters of *O*-glycosylic disaccharide chains. . .," *Carbohydrate Research*, 116, c9-c12, 1983 (Ex. 2);
2. M. Elofsson et al., "Preparation of Tn and Sialyl Tn Building Blocks. . .," *Tetrahedron*, 53, 369-390, 1997 (Ex. 3);
3. M. Elofsson and J. Kihlberg, "Synthesis of Tn and Sialyl Tn building Blocks for Solid Phase Glycopeptide Synthesis," *Tetrahedron Letters*, 36, 7499-7502, 1995 (Ex. 4);
4. P. Fung et al., "Active Specific Immunotherapy of Murine Mammary. . .," *Cancer Research*, 50, 4308-4314, 1990 (Ex. 5);
5. R. Gleiter et al., "Synthesis and Properties of Eight-and Ten-Membered Selenaradialenes," *Tetrahedron Letters*, 35, 8779-8782, 1994 (Ex. 6);
6. P. Grice et al., "Turning the Reactivity of Glycosides: Efficient One-pot Oligosaccharide Synthesis," *SYNLETT*, 781-784, 1995 (Ex. 7);
7. A. Kameyama et al., "Total Synthesis of Sialyl Lewis X\*," *Carbohydrate Research*, 209, c1-c4, 1991 (Ex. 8);
8. H. Kondo et al., "In vitro action of human and porcine  $\alpha$ -amylases. . .," *Carbohydrate Research*, 204, 207-213, 1990 (Ex. 9);
9. H. Kunz et al., "Construction of Disaccharide N-Glycopeptides. . .," *Angew. Chem. Int. Ed. Engl.*, 24, 883-885, 1985 (Ex. 10);
10. H. Kunz et al., "Synthesis of *O*-Glycopeptides of the Tumor-Associated T<sub>N</sub> . . .," *Angew. Chem. Int. Ed. Engl.*, 25, 360-362, 1986 (Ex. 11);

11. B. Liebe and Horst Kunz, "Solid Phase Synthesis of a Tumor-Associated Sialyl-T<sub>N</sub> Antigen Glycopeptide. . .," *Angew. Chem. Int. Ed. Engl.* 33, 618-621, 1997 (Ex. 12);
12. H. Lönn, "Synthesis of a Tri- and a Hepta-saccharide. . .," *Carbohydrate Research*, 139, 105-113, 1985 (Ex. 13);
13. K.C. Nicolaou *et al.*, "Stereocontrolled Synthesis of Sialyl Lex, . . .," *J. Chem. Soc., Chem. Commun.*, 870-872, 1991 (Ex. 14);
14. P. Schultheiss-Riemann *et al.*, "O-Glycopeptide Synthesis. . .," *Angew. Chem. Int. Ed. Engl.*, 22, 62-63, 1983 (Ex. 15).

Copies of the above-listed documents (Exhibits 2-15) are submitted herewith. In addition, these documents are listed on Form PTO-1449B which is attached hereto (Exhibit 1). To the extent that a document is listed and no copy thereof is attached, then such document is not at present available to the undersigned, or is available in the file of a prior related application relied upon for an earlier filing date under 35 USC §120. 37 CFR §1.98(d).<sup>1</sup>

Applicants respectfully solicit the Examiner's consideration of the documents and entry into the record of this application. The citation of any document in the

---

If a listed document is not in the English language and an English translation is readily available, such translation is also attached; if a translation is not attached, it is not readily available to the undersigned. If a foreign language document is cited, and an English language equivalent is known to the undersigned, then such equivalent patent is also cited on the attached form along with the corresponding foreign language patent, and a connecting arrow indicated therebetween; if no such English language equivalent is cited, then none is known to the undersigned.

In re Application of Samuel J. Danishefsky et al.  
Serial No.: 09/042,280  
Filed: January 13, 1997

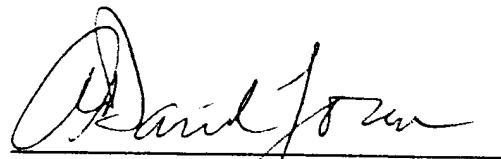
1078/1B925US1

present Information Disclosure Statement is not to be construed as an admission that such document is necessarily relevant or is prior art.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

No fee is believed necessary in connection with the filing of this Information Disclosure Statement since it is being filed prior to the issuance of a first Official Action on the merits. 37 CFR §1.97(b)(3). However, if a first Official Action on the merits is mailed on or before the submission date of this Information Disclosure Statement, or any fee is otherwise deemed required, authorization is hereby given to charge the amount of such fee to Deposit Account 50-0540.

Respectfully submitted,

  
A. David Joran  
Registration No. 37,858  
Attorney for Applicants

KRAMER, LEVIN, NAFTALIS & FRANKEL LLP  
919 Third Avenue  
New York, New York 10022  
212-715-9100

09/833327  
04/12/01

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2	Attorney Docket Number	1078/1B925US1
-------	---	----	---	------------------------	---------------

## Complete if known

Application Number	Serial No. 09/042,280
Filing Date	January 13, 1997
First Named Inventor	Samuel J. Danishefsky
Group Art Unit	1623
Examiner Name	Lee, H.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials <sup>1</sup>	Cite No. <sup>2</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		V. Bencomo <i>et al.</i> , "Synthesis of glycopeptides having clusters of O-glycosylic disaccharide chains. . .," <i>Carbohydrate Research</i> , <u>116</u> , c9-c12, 1983 (Ex. 2)
		M. Elofsson <i>et al.</i> , "Preparation of Tn and Sialyl Tn Building Blocks. . .," <i>Tetrahedron</i> , <u>53</u> , 369-390, 1997 (Ex. 3)
		M. Elofsson and J. Kihlberg, "Synthesis of Tn and Sialyl Tn building Blocks for Solid Phase Glycopeptide Synthesis," <i>Tetrahedron Letters</i> , <u>36</u> , 7499-7502, 1995 (Ex. 4)
		P. Fung <i>et al.</i> , "Active Specific Immunotherapy of Murine Mammary....," <i>Cancer Research</i> , <u>50</u> , 4308-4314, 1990 (Ex. 5)
		R. Gleiter <i>et al.</i> , "Synthesis and Properties of Eight-and Ten-Membered Selenaradialenes," <i>Tetrahedron Letters</i> , <u>35</u> , 8779-8782, 1994 (Ex. 6)
		P. Grice <i>et al.</i> , "Turning the Reactivity of Glycosides: Efficient One-pot Oligosaccharide Synthesis," <i>SYNLETT</i> , 781-784, 1995 (Ex. 7)
		A. Kameyama <i>et al.</i> , "Total Synthesis of Sialyl Lewis X*," <i>Carbohydrate Research</i> , <u>209</u> , c1-c4, 1991 (Ex. 8)
		H. Kondo <i>et al.</i> , "In vitro action of human and porcine $\alpha$ -amylases. . .," <i>Carbohydrate Research</i> , <u>204</u> , 207-213, 1990 (Ex. 9)
		H. Kunz <i>et al.</i> , "Construction of Disaccharide N-Glycopeptides. . .," <i>Angew.Chem. Int. Ed. Engl.</i> , <u>24</u> , 883-885, 1985 (Ex. 10)
		H. Kunz <i>et al.</i> , "Synthesis of O-Glycopeptides of the Tumor-Associated T <sub>N</sub> . . .," <i>Angew. Chem. Int. Ed. Engl.</i> , <u>25</u> , 360-362, 1986 (Ex. 11)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231.  
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

09/03/2001  
04/12/01  
U.S. PTO

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if known

Application Number	Serial No. 09/042,280
Filing Date	January 13, 1997
First Named Inventor	Samuel J. Danishefsky
Group Art Unit	1623
Examiner Name	Lee, H.

Attorney Docket Number 1078/1B925US1

Sheet

2

of

2

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>2</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>3</sup>
		B. Liebe and Horst Kunz, "Solid Phase Synthesis of a Tumor-Associated Sialyl-T <sub>N</sub> Antigen Glycopeptide. . .," <i>Angew. Chem. Int. Ed. Engl.</i> <u>33</u> , 618-621, 1997 (Ex. 12)	
		H. Lönn, "Synthesis of a Tri- and a Hepta-saccharide. . .," <i>Carbohydrate Research</i> , <u>139</u> , 105-113, 1985 (Ex. 13)	
		K.C. Nicolaou <i>et al.</i> , "Stereocontrolled Synthesis of Sialyl Le <sup>x</sup> . . .," <i>J. Chem. Soc., Chem. Commun.</i> , 870-872, 1991 (Ex. 14)	
		P. Schultheiss-Riemann <i>et al.</i> , "O-Glycopeptide Synthesis. . .," <i>Angew. Chem. Int. Ed. Engl.</i> , <u>22</u> , 62-63, 1983 (Ex. 15)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231.  
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(use as many sheets as necessary)*

Sheet

2

of

2

**Complete if known**

Application Number	Serial No. 09/042,280
Filing Date	January 13, 1997
First Named Inventor	Samuel J. Danishefsky
Group Art Unit	1623
Examiner Name	Lee, H.
Attorney Docket Number	1078/1B925US1

JC929 U.S. PTO  
09/03/27  
04/12/01

**OTHER PRIOR ART — NON PATENT LITERATURE DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SU		B. Liebe and Horst Kunz, "Solid Phase Synthesis of a Tumor-Associated Sialyl-T <sub>N</sub> Antigen Glycopeptide. . .," <i>Agnew. Chem. Int.Ed. Engl.</i> , <u>33</u> , 618-621, 1997 (Ex. 12)	
		H. Lönn, "Synthesis of a Tri- and a Hepta-saccharide. . .," <i>Carbohydrate Research</i> , <u>139</u> , 105-113, 1985 (Ex. 13)	
		K.C. Nicolaou <i>et al.</i> , "Stereocontrolled Synthesis of Sialyl Le", . . ., <i>J. Chem. Soc., Chem. Commun.</i> , 870-872, 1991 (Ex. 14)	
↓		P. Schultheiss-Riemann <i>et al.</i> , "O-Glycopeptide Synthesis. . .," <i>Angew. Chem. Int. Ed. Engl.</i> , <u>22</u> , 62-63, 1983 (Ex. 15)	

Examiner Signature	<i>N. Uyan</i>	Date Considered	12/3/99
--------------------	----------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.